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The Patent Office

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1. Your Reference

CGP/PG4029

2. Patent application number

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Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its corporation

473.587003

4. Title of the invention

REMOTE PATIENT ASSESSMENT SYSTEM

5. Name of your agent (if you have one)

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Country

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8. Is a statement of inventorship and of right to grant a patent required in support of this request? (Answer yes if:

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Description 17

Claim(s) 8

Abstract 1

Drawing(s) 4 + 4 14

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Statement of inventorship and right
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Request for substantive examination
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11.

I/We request the grant of a patent on the basis of this application



Signature Christopher Gerard Pike
AGENT FOR THE APPLICANTS

08 May 2000

12. Name and daytime telephone number of
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Remote patient assessment system

5 The present invention relates to a system for the remote assessment of the medical condition of a patient. The system has an electronic data collection system and is capable of wireless communication with an entrypt to a network computer system to enable communication of data between the network computer system and the electronic data collection system.

10 It is common prescribing practice for a doctor to prescribe a patient with medicament in a medicament dispenser together with instructions for patient administration of the medicament according to a defined treatment regime. The patient typically therefore, receives instructions relating to the correct use of the dispenser together with recommended dosing amounts, dose intervals and
15 treatment period. The patient is then trusted to follow the treatment regime as set by the doctor.

A limitation associated with this practice is that the treatment regime is set at the time of prescription and can therefore not account for changes in the patient's
20 condition over the treatment period. A further limitation associated with this practice is that the onus is on the patient to comply with the doctor's instructions. Occasionally, patients will forget to take the medicament or will vary the treatment regime in an unpredictable manner with possible consequences for the success of the treatment.

25 A variation on the above-described prescribing practice involves the use by a patient of a diagnostic device which enables data relating to their medical condition to be gathered on a regular basis. This data may for example, be collected prior to administration of any medicament and a correct dose amount
30 calculated on the basis of the diagnostic data. An example of this practice would be that of a diabetic who checks their blood-sugar levels in order to calculate a required dose of insulin.

35 In developments of the practice variation, the diagnostic device may be integrated with the delivery system. Information relating to the patient's condition

and usage of the dispenser may thus be displayed to the patient to enable the better management of their medical condition. The information may further be stored in a memory such that it may be recalled at a later time to enable historic analysis of the progress of the condition and effect of the treatment. Dispensers
5 employing electronic data management systems have been proposed for this purpose.

US-A-5,363,842 describes an inhalation device for use in delivering inhalable medicament. The device enables data relating to the patient's breathing pattern
10 to be collected, analysed and displayed to the patient. The data is stored in a memory for download to a workstation at the clinic.

WO99/35588 describes a method for managing the administration of medicine and in particular, monitoring patient compliance with a prescribed treatment
15 regime. The method relies on input of patient data to a central computer workstation. The central computer workstation calculates and transmits dosage data to a dispensing device via a communications link. The dispensing device delivers drug in accord with the dosage data.

The Applicants have now developed an improved system for the remote assessment of a patient which employs an electronic data collection system. The system is capable of communication with an entryptpoint to a network computer system to enable communication of data between the network computer system and the electronic data collection system. The system therefore, provides the
20 advantage of enabling transfer of patient assessment data to a network of computers, which network can be made accessible to diverse remote datasources, which may in turn be networked together for cross-transfer of data. The patient and authorised users can therefore, have ready access to patient assessment data and to diverse, possibly inter-connected, remote information
25 sources capable of providing disease management information. In turn, the system can feed information, such as compliance data, back to any authorised user having access to the computer network system.

The system can be further configured to allow selective access to data
35 depending upon level of user authorisation. Still further, the system can be

integrated with a system for the provision of electronic prescriptions to enable seamless remote assessment and prescription of medicament.

5 According to one aspect of the present invention there is provided a system for the remote assessment of a patient's medical condition comprising a network computer system having specifiable network addresses; remote from said network computer system, a patient electronic data collection system for locally collecting data relevant to the patient's medical condition; a communicator for wirelessly communicating with an entrypt to said network computer system to enable transfer of said data to a network address of the network computer system, wherein said network address is specific to the patient; and a secure access gateway enabling authorised users only to access the data at said patient-specific network address.

15 By remote it is meant that the patient electronic data collection system is physically, and potentially geographically distant from the entrypt to the network computer system. In embodiments, it is envisaged that the patient data collection system is designed to be kept under the control of the patient e.g. it may be worn by the patient or be a handheld device always carried by the patient. Examples of patient-wearable devices would include belt attachable devices, devices in the form of watches for wrist or leg attachment and devices attachable as jewellery. Suitable body attachment means will be incorporated as required.

25 The communicator is local to the patient, for example being on the patient data collection system, or within another handheld device or present in the home or working environment of the patient. The communicator may for example, be in a device which mechanically coupled to a device housing the patient data collection system by any suitable mechanical mechanism including grip mechanisms and snap-fit mechanisms. In a preferred aspect, the data communicator forms a snap-in module and the device housing the patient data collection system is shaped for receipt of the module.

35 The network computer system by contrast, is typically located at, and under the control of, a healthcare provider or manager such as a doctor's practice, a

hospital or a healthcare management centre. It is an advantage of the system herein, that the network computer system may be located geographically distant from the patient.

5 In one aspect, the patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a regular basis.

10 In another aspect, the patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a continuous basis.

15 Suitably, the patient monitoring system forms part of a compliance monitoring system arranged to monitor patient compliance with a particular treatment regime.

20 Suitably, the patient electronic data collection system forms part of a medicament delivery system and is arranged to collect data when the patient uses the medicament delivery system.

In embodiments, the medicament delivery system provides respirable delivery of medicament to the patient or injectable delivery of medicament to the patient or is an implant in the body of the patient.

25 Suitably, the medicament delivery system includes a predictive algorithm or look-up table for calculating the optimum amount of medicament to dispense. Suitably, the medicament delivery system has a memory including a dose memory for storing dosage data and reference is made to the dose memory in calculating the optimum amount of medicament to dispense.

30 Suitably, the medicament delivery system additionally comprises a selector for selecting the amount of medicament to deliver. In one aspect, the selector is manually operable. In another aspect, the selector is operable in response to a signal from a transmitter.

35

Preferably, the system additionally comprises a detector for detecting dispensing from the medicament container, wherein said detector communicates dispensing data to the electronic data management system.

- 5 Suitably, the data is communicable between the patient electronic data collection system and the patient-specific network address of the network computer system in encrypted form. All suitable methods of encryption or partial encryption are envisaged. Password protection may also be employed.
- 10 In one aspect, the data is continuously communicable between the patient electronic data collection system and the patient-specific network address of the network computer system.
- 15 In another aspect, the data is communicable in packet form between the patient electronic data collection system and the patient-specific network address of the network computer system.
- Suitably, the secure access gateway is password protected.
- 20 Suitably, the secure access gateway enables different levels of access authorisation to the data to be assigned to different authorised users.
- 25 Suitably, the authorised users are selected from the group consisting of the patient, a healthcare professional such as a doctor or nurse, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof.
- Suitably, information from a patient-remote datasource is made available to the patient-specific network address.
- 30 In one aspect, the patient-remote datasource comprises data relating to ambient environmental conditions such as weather conditions, or pollution, smog and pollen levels.

In another aspect, the patient-remote datasource comprises a database of prescribable medicaments. The database may be arranged to focus on medicaments of particular applicability to the patient's condition and to be the subject of regular update as new medicaments are released to the market.

5

The patient-remote datasource may, for example be managed by a medicament prescriber, for example a doctor's practice. Information transferred from the medicament prescriber may thus, comprise changes to prescription details, automatic prescription updates or training information. Information transferred to the medicament prescriber may comprise compliance information, that is to say information relating to the patient's compliance with a set-prescribing programme. Patient performance information relating for example, to patient-collected diagnostic data may also be transferred to the medicament prescriber.

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15

In another aspect, the patient-remote datasource is managed by a pharmacy. Information transferred from the pharmacy may thus, comprise information relating to the medicament product. Information sent to the pharmacy may thus include prescription requests which have been remotely pre-authorized by the medicament prescriber.

20

In a further aspect, the patient-remote datasource is an emergency assistance provider, for example a hospital accident and emergency service or an emergency helpline or switchboard. The information may thus, comprise a distress or emergency assist signal which requests emergency assistance.

25

In a further aspect, the patient-remote datasource is a manufacturer of medicament or medicament delivery systems. Information transferred to the system may thus, comprise product update information. The system may also be configured to feed information back to the manufacturer relating to system performance.

30

In a further aspect, the patient-remote datasource is a research establishment. In a clinical trials situation, information may thus be transferred relating to the trials protocol and information relating to patient compliance fed back to the research establishment.

35

Suitably, the patient electronic data collection system further comprises a patient electronic data management system comprising a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.

Suitably, the patient electronic data management system additionally comprises a geographic positioning system such as a global positioning system or a system which relies on the use of multiple communications signals and a triangulation algorithm.

Suitably, the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system.

Suitably, the system additionally comprises an authorised user data communicator comprising an authorised user electronic data management system comprising a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data; and a communicator for wirelessly communicating with an endpoint to a network computer system to enable communication of data between the network computer system and the authorised user electronic data management system.

According to another aspect of the present invention there is provided a system for the remote assessment of a patient's medical condition and remote prescription therefor comprising a system as described above and additionally a first authorised user data communicator capable of communicating a prescription authorisation command to the patient-specific network address; and a second authorised user data communicator capable of receiving a prescription authorisation command from the patient-specific network address.

Suitably, any communicator employs radiofrequency or optical signals.

In one aspect, any communicator communicates directly with the gateway.

In another aspect, any communicator communicates with the gateway via a second communications device. Suitably, the second communications device is a telecommunications device, more preferably a cellular phone or pager.

5 Suitably, the communicator communicates with the second communications device using spread spectrum radiofrequency signals. A suitable spread spectrum protocol is the Bluetooth (trade mark) standard which employs rapid (e.g. 1600 times a second) hopping between plural frequencies (e.g. 79 different frequencies). The protocol may further employ multiple sending of data bits (e.g.
10 sending in triplicate) to reduce interference.

In one aspect, the network computer system comprises a public access network computer system. The internet is one suitable example of a public access network computer system, wherein the entypoint can be any suitable entypoint
15 thereto including gateways managed by an internet service provider. The public access network computer system may also form part of a telecommunications system, which may itself be either a traditional copper wire system, a cellular system or an optical network.

20 In another aspect, the network computer system comprises a private access network computer system and the entypoint is a secure gateway. The private access network system may for example, comprise an intranet or extranet which may for example, be maintained by a healthcare service provider or medicament manufacturer. The secure gateway may for example include password
25 protection; a firewall; and suitable encryption means.

Suitably, the communicator enables communication with a user-specific network address in the network computer system. The user-specific network address may be selected from the group consisting of a web-site address, an e-mail
30 address and a file transfer protocol address.

Suitably, the patient electronic data management system additionally comprises a datalink for linking to a local data store such as a personal computer or set-top box to enable communication of data between the local data store and the

microprocessor. Preferably, the datalink comprises an infrared emitter and sensor.

5 Suitably, the patient electronic data management system additionally comprises a data input system for user input of data to the electronic data management system. More preferably, the data input system comprises a keypad.

10 Suitably, the patient electronic data management system additionally comprises a display for display of data from the electronic data management system to the user. The display may for example, comprise a screen such as an LED or LCD screen.

15 In one aspect, the system is suitable for the remote assessment of a patient's respiratory condition and additionally comprises a sensor which senses the breath of a user, wherein the sensor communicates breath data to the patient electronic data collection system.

20 Suitably, the sensor comprises a breath-movable element which is movable in response to the breath of a patient. Preferably, the breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

25 ~~In a further aspect, the sensor comprises an~~ airflow sensor for sensing the airflow profile associated with the breath of a user.

30 In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. The temperature of the inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool.

In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. The moisture content of the

inhaled and exhaled part of the breath cycle varies and this also may be used as a measurement tool.

5 In a further aspect, the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user. The chemical profile of the inhaled and exhaled part of the breath cycle varies and this further may be used as a measurement tool.

10 Preferably, the breath data includes breath cycle data or peak flow data.

In one aspect, the system is suitable for the delivery of respirable medicament and additionally comprises a sensor which senses the breath of a user, wherein the sensor communicates breath data to the electronic data management system.

15 Preferably, the system additionally comprises an actuator for actuating the dispensing mechanism, said actuator being actuable in response to a trigger signal from the transmitter.

20 Preferably, the electronic data management system includes a predictive algorithm or look-up table for deriving from the breath data when to transmit the trigger signal. For example, a real-time analysis of the patient breath waveform may be made and the trigger point derived by reference to that analysed waveform.

25 In one preferred aspect, the medicament container is an aerosol container and the dispensing mechanism is an aerosol valve.

30 In another preferred aspect, the medicament container is a dry-powder container, that is to say a container suitable for containing medicament in dry-powder form.

35 Preferably, the actuator comprises an energy store for storing energy which energy is releasable to actuate the dispensing mechanism of the medicament container. The energy store comprises in preferred aspects, a biasable resilient

member such as a spring, a source of compressed fluid such as a canister of compressed gas or a battery. Chemical energy sources are also suitable and might include chemical propellant or ignition mixtures. Other sources might include physical explosives such as liquefied or solidified gas in a canister which
5 burst when heated or exposed to the atmosphere.

The system may additionally comprise a safety mechanism to prevent unintended multiple actuations of the actuator. The patient is thereby protected from inadvertently receiving multiple doses of medicament in a situation where
10 they take a number of short rapid breaths. More preferably, the safety mechanism imposes a time delay between successive actuations of the actuator. The time delay is typically of the order of from three to thirty seconds.

An actuation counter which can be mechanical or electronic may be provided to
15 the system.

A medicament dispensing counter, such as a dose counter, may be provided to the system. This may be mechanical or electronic. The counter may be coupled to a visual display to provide feedback to the patient as to amount of drug
20 released or remaining in the container.

A manual override can be provided to the system for use in the event of emergency or system failure.

25 In another aspect, the system is suitable for the remote assessment of a patient's cardiovascular condition and additionally comprises a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system. Preferably, the sensor measures the blood pressure of the patient.
30

According to another aspect of the present invention there is provided a method for remotely assessing a patient's medical condition comprising locally collecting data relevant to the patient's medical condition in electronic form; wirelessly communicating with an endpoint to a remote network computer system to
35 enable transfer of said data to a patient-specific network address of said remote

network computer system; and permitting authorised users to access the data at said patient-specific network address via a secure access gateway.

Suitably, the method comprises collecting the data on a regular basis.

5

Suitably, the method comprises collecting the data on a continuous basis.

Suitably, the method comprises wirelessly communicating the data in encrypted form.

10

In one aspect, the data is continuously communicable. In another aspect, the data is communicable in packet form.

15

Suitably, the method comprises permitting different levels of access to the data to different authorised users.

20

In one aspect the method is suitable for remotely assessing a patient's condition and remotely prescribing therefor and additionally comprises a first authorised user communicating a prescription authorisation command to the patient-specific network address; a second authorised user receiving said prescription authorisation command from the patient-specific network address; and said second authorised user preparing the prescription based on the prescription authorisation.

25

In another aspect, the method is suitable for remotely assessing a patient's condition and remotely prescribing therefor and additionally comprises a first authorised user communicating a prescription authorisation command to a pharmacy network address; a second authorised user receiving said prescription authorisation command from the pharmacy network address; and said second authorised user preparing the prescription for the patient based on the prescription authorisation.

30

Suitably, the first authorised user communicates the prescription authorisation in response to a 'update prescription' alerting signal visible at the patient-specific network address. The 'update prescription' signal is typically based on data

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communicated from the patient data collection system which may for example, reflect a change in the patient's condition. In one aspect, where the patient data collection system forms part of a medicament delivery system the 'update prescription' signal may be an alert that the levels of medicament in the delivery system are running low and that a re-prescription is needed.

Embodiments of systems according to the invention will now be described with reference to the accompanying drawings in which:

Figure 1. is a schematic representation of a first system in accord with the present invention in which the patient electronic data collection system forms part of a medicament delivery system;

Figure 2. is a schematic representation of a second system in accord with the present invention in which the patient electronic data collection system forms part of a medicament delivery system; and

Figures 3 and 4 are schematic representations of third and fourth systems in accord with the present invention in which the patient remote assessment system integrates with a system for electronic prescription of medicament.

Figure 1. shows a standard-form metered dose inhaler for the delivery of inhalable medicament comprising a tubular housing 10 in which an aerosol container 12 is located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. A dispensing outlet 14 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 14 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

The aerosol container 12 is located in the housing 10 so that one end protrudes from the open top of the housing 10. The aerosol container 12 has an outlet valve stem (not visible) at one end which connects with a support (not shown) in the housing 10. To dispense the dose, the protruding portion of the aerosol container 12 is depressed to move the container 12 relative to the valve stem to

open the valve and dispense medicament into the outlet 14 from which it can be inhaled by a patient.

5 The dispenser includes an electronic data management system in the form of a chip comprised within the housing (not visible). The user may access the electronic data management system by use of push-buttons 20 and toggle menu-button 24. Display 30 allows for display of menu choices and data from the electronic data management system. The dispenser communicates via communications chip 40 to computer network system 50. The computer network system 50 comprises a secure extranet computer system. Remote information sources 60, 62, 64, 66, 68 also have access to the extranet. In more detail, the remote information sources comprise a medicament prescriber 60, a pharmacy 62, a weather monitoring station 64, a pollution monitoring station 66 and a medicament manufacturer 68. Two-way data transfer is possible between the electronic data management system and the computer network system 50 via the communications chip 40. Information transfer is thus possible between the electronic data management system and any of the remote information sources 60, 62, 64, 66, 68.

20 Figure 2. shows a variation of the system of Figure 2. The system comprises standard-form metered dose inhaler for the delivery of inhalable medicament comprising tubular housing 110, an aerosol container 112 and dispensing outlet 114. Operation of the inhaler is as described above with reference to Figure 1.

25 The dispenser includes an electronic data management and communications system in the form of a chip 140 comprised within the housing 110. Display 130 allows for limited display data from the electronic data management system. The dispenser readily communicates via chip 140 to palmtop computer 170. The communication is via spread spectrum radiofrequency signals operable over a relatively short range (e.g. up to ten metres). The palmtop computer 170 has a more sophisticated display 172 including a graphical user interface comprising menu-entry screens from which selections may be made using toggle menu-button 174.

The user accesses the electronic data management system 140 of the dispenser through the palmtop computer 170. The palmtop computer 170 itself, can communicate through a telecommunications link with computer network system 150. The computer network system 150 comprises a secure extranet computer system. As in Figure 1, remote information sources may also have access to the extranet. Two-way data transfer is possible between the electronic data management system and the computer network system 150 via the communications links with the palmtop computer 170. Information transfer is thus possible between the electronic data management system 140, palmtop computer 170 and any of the remote information sources.

Figure 3 shows a system herein in which patient electronic data collection system 240 communicates wirelessly with geographically distant network computer system 250. The network computer system 250 is itself wirelessly accessible by the system of a medicament prescriber 260 (e.g. a doctor's surgery system) and by the system of a pharmacist 262.

The system of Figure 3 may be employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data collection system 240 communicates data relating to the medical condition of the patient to the network computer system 250. The medicament prescriber 260 wirelessly accesses this data e.g. by use of a palmtop communications and data management device and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the network computer system 250. The pharmacist 262 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises them to make up the prescription for the patient.

The system of Figure 4 is a variation of the system of Figure 3 in which patient electronic data collection system 340 communicates wirelessly with geographically distant network computer system 350. The network computer system 350 is itself wirelessly accessible by the system of a medicament prescriber 360 (e.g. a doctor's surgery system). The prescriber system 360 may also access second network computer system 354 which is accessible by the system of a pharmacist 362. In an alternative herein, the second computer

system 354 may be integral with the system of the pharmacist 362 or be a dedicated secure prescription system accessible only to the prescriber and the pharmacist.

- 5 The system of Figure 4 be employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data collection system 340 communicates data relating to the medical condition of the patient to the network computer system 350. The medicament prescriber 360 wirelessly accesses this data and makes a judgement as to prescription needs. If a new prescription is
10 needed the prescriber sends a 'prescription authorisation' signal to the second network computer system 354. The pharmacist 362 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises the pharmacist to make up the prescription for the patient.
- 15 The medicament delivery system aspect of the invention is in one aspect suitable for dispensing medicament for the treatment of respiratory disorders such as disorders of the lungs and bronchial tracts including asthma and chronic obstructive pulmonary disorder (COPD).
- 20 Appropriate medicaments may be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g.,
25 methapyrilene; anti-inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol,
30 rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins
35 and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the

art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

5

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

10

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

15

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

20

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more

25

of the following claims:

CLAIMS:

1. A system for the remote assessment of a patient's medical condition comprising

a network computer system having specifiable network addresses;

remote from said network computer system, a patient electronic data collection system for locally collecting data relevant to the patient's medical condition;

a communicator for wirelessly communicating with an endpoint to said network computer system to enable transfer of said data to a network address of the network computer system, wherein said network address is specific to the patient; and

a secure access gateway enabling authorised users only to access the data at said patient-specific network address.

2. A system according to claim 1, wherein said patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a regular basis.

3. A system according to claim 2, wherein the patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a continuous basis.

4. A system according to any of claims 1 to 3, wherein said patient monitoring system forms part of a compliance monitoring system arranged to monitor patient compliance with a particular treatment regime.

5. A system according to any of claims 1 to 4, wherein the patient electronic data collection system forms part of a medicament delivery system and is arranged to collect data when the patient uses the medicament delivery system.

6. A system according to claim 5, wherein the medicament delivery system provides respirable delivery of medicament to the patient.

5 7. A system according to claim 5, wherein the medicament delivery system provides injectable delivery of medicament to the patient.

8. A system according to claim 5, wherein the medicament delivery system is an implant in the body of the patient.

10 9. A system according to any of claims 1 to 8, wherein the data is communicable between the patient electronic data collection system and the patient-specific network address of the network computer system in encrypted form.

15 10. A system according to any of claims 1 to 9, wherein the data is continuously communicable between the patient electronic data collection system and the patient-specific network address of the network computer system.

20 11. A system according to any of claims 1 to 10, wherein the data is communicable in packet form between the patient electronic data collection system and the patient-specific network address of the network computer system.

25 12. A system according to any of claims 1 to 11, wherein the secure access gateway is password protected.

30 13. A system according to any of claims 1 to 12, wherein the secure access gateway enables different levels of access authorisation to the data to be assigned to different authorised users.

35 14. A system according to any of claims 1 to 13, wherein the authorised users are selected from the group consisting of the patient, a healthcare professional, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof.

15. A system according to any of claims 1 to 14, wherein information from a patient-remote datasource is made available to the patient-specific network address.

5

16. A system according to claim 15, wherein the patient-remote datasource comprises data relating to ambient environmental conditions.

10

17. A system according to claim 15, wherein the patient-remote datasource comprises a database of prescribable medicaments.

15

18. A system according to any of claims 1 to 17, wherein the patient electronic data collection system further comprises a patient electronic data management system comprising

a memory for storage of data;

a microprocessor for performing operations on said data; and

20

a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.

25

19. A system according to claim 18, wherein said patient electronic data management system additionally comprises a geographic positioning system.

20. A system according to either of claims 18 or 19, wherein the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system.

30

21. A system according to any of claims 1 to 20, additionally comprising an authorised user data communicator comprising

an authorised user electronic data management system comprising

35

a memory for storage of data;

a microprocessor for performing operations on said data; and

5 a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data; and

a communicator for wirelessly communicating with an entrapment to a network computer system to enable communication of data between the network computer system and the authorised user electronic data management system.

10 22. A system according to claim 21 for the remote assessment of a patient's medical condition and remote prescription therefor comprising

15 a first authorised user data communicator capable of communicating a prescription authorisation command to the patient-specific network address; and

a second authorised user data communicator capable of receiving a prescription authorisation command from the patient-specific network address.

20 23. A system according to any of claims 1 to 22, wherein any communicator employs radiofrequency or optical signals.

24. A system according to any of claims 1 to 23, wherein any communicator communicates directly with the network computer system.

25 25. A system according to any of claims 1 to 24, wherein any communicator communicates with the network computer system via a second communications device.

30 26. A system according to claim 25, wherein the second communications device is a telecommunications device.

35 27. A system according to claim 26, wherein the telecommunications device comprises a cellular phone or pager.

28. A system according to any of claims 25 to 27, wherein the communicator communicates with the second communications device using spread spectrum radiofrequency signals.

5 29. A system according to any of claims 1 to 28, wherein the network computer system comprises a public access network computer system.

30. A system according to any of claims 1 to 29, wherein the network computer system comprises a private access network computer system.

10

31. A system according to any of claims 1 to 30, wherein the patient-specific network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address.

15

32. A system according to any of claims 18 to 31, wherein the patient electronic data management system additionally comprises a data input system for patient input of data to the electronic data management system.

20

33. A system according to claim 32, wherein said data input system comprises a keypad.

25

34. A system according to any of claims 18 to 33, additionally comprising a display for display of data from the patient electronic data management system to the patient.

30

35. A system according to any of claims 1 to 34 for the remote assessment of a patient's respiratory condition additionally comprising a sensor which senses the breath of a user, wherein the sensor communicates breath data to the patient electronic data collection system.

35

36. A system according to claim 35, wherein said sensor comprises a breath-movable element which is movable in response to the breath of a patient.

37. A system according to claim 36, wherein said breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

38. A system according to claim 35, wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

5

39. A system according to claim 35, wherein the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

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40. A system according to claim 35, wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user.

15

41. A system according to claim 35, wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user.

20

42. A system according to claim 35, wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user.

43. A system according to any of claims 35 to 42, wherein said breath data includes breath cycle data.

25

44. A system according to any of claims 35 to 42, wherein said breath data includes peak flow data.

30

45. A system according to any of claims 1 to 34 for the remote assessment of a patient's cardiovascular condition additionally comprising a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system.

46. A system according to claim 45, wherein said sensor measures the blood pressure of the patient.

47. A method for remotely assessing a patient's medical condition comprising

5 locally collecting data relevant to the patient's medical condition in electronic form;

wirelessly communicating with an entryptpoint to a remote network computer system to enable transfer of said data to a patient-specific network address of said remote network computer system; and

10 permitting authorised users to access the data at said patient-specific network address via a secure access gateway.

48. A method according to claim 47, comprising collecting the data on a regular basis.

49. A method according to claim 47, comprising collecting the data on a continuous basis.

20 50. A method according to any of claims 47 to 49, comprising wirelessly communicating the data in encrypted form.

51. A method according to any of claims 47 to 50, wherein the data is continuously communicable.

25 52. A method according to any of claims 47 to 50, wherein the data is communicable in packet form.

53. A method according to any of claims 47 to 52, comprising permitting different levels of access to the data to different authorised users.

30 54. A method according to any of claims 47 to 53 for remotely assessing a patient's condition and remotely prescribing therefor additionally comprising

a first authorised user communicating a prescription authorisation command to the patient-specific network address;

5 a second authorised user receiving said prescription authorisation command from the patient-specific network address; and

said second authorised user preparing the prescription based on the prescription authorisation.

10 55. A method according to any of claims 47 to 53 for remotely assessing a patient's condition and remotely prescribing therefor additionally comprising

15 a first authorised user communicating a prescription authorisation command to a pharmacy network address;

a second authorised user receiving said prescription authorisation command from the pharmacy network address; and

20 said second authorised user preparing the prescription for the patient based on the prescription authorisation.

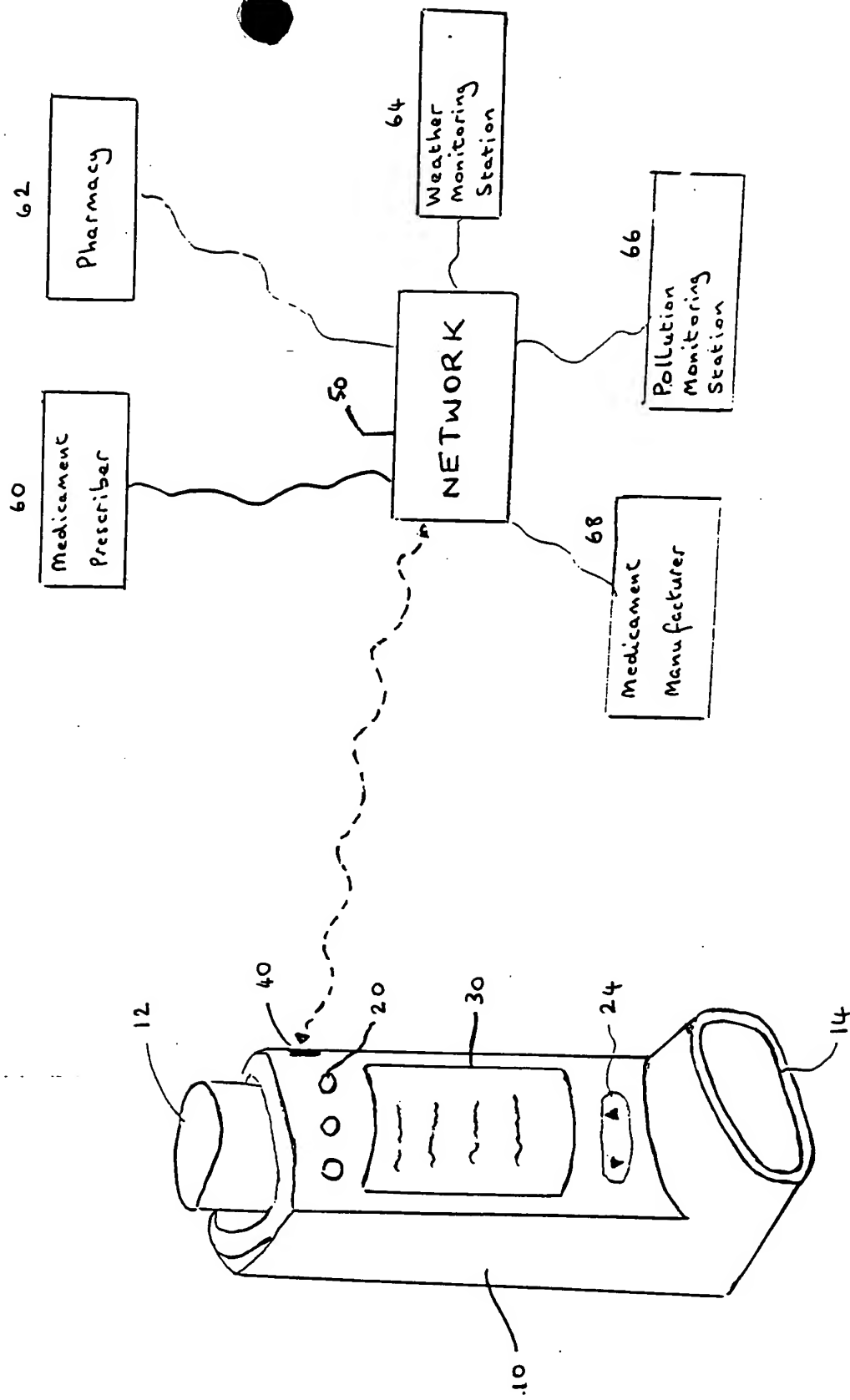
25 56. A method according to either of claims 54 or 55, wherein the first authorised user communicates the prescription authorisation in response to a 'update prescription' alerting signal visible at the patient-specific network address.

ABSTRACT

5 There is provided a system for the delivery of medicament comprising a
medicament container; a dispensing mechanism for dispensing medicament
from the medicament container; and a communicator for wireless communication
with a gateway to a network computer system to enable communication of data
between the network computer system and the electronic data management
system. The electronic data management system comprises a memory for
storage of data; a microprocessor for performing operations on the data; and a
10 transmitter for transmitting a signal relating to the data or the outcome of an
operation on the data.

Fig. 1

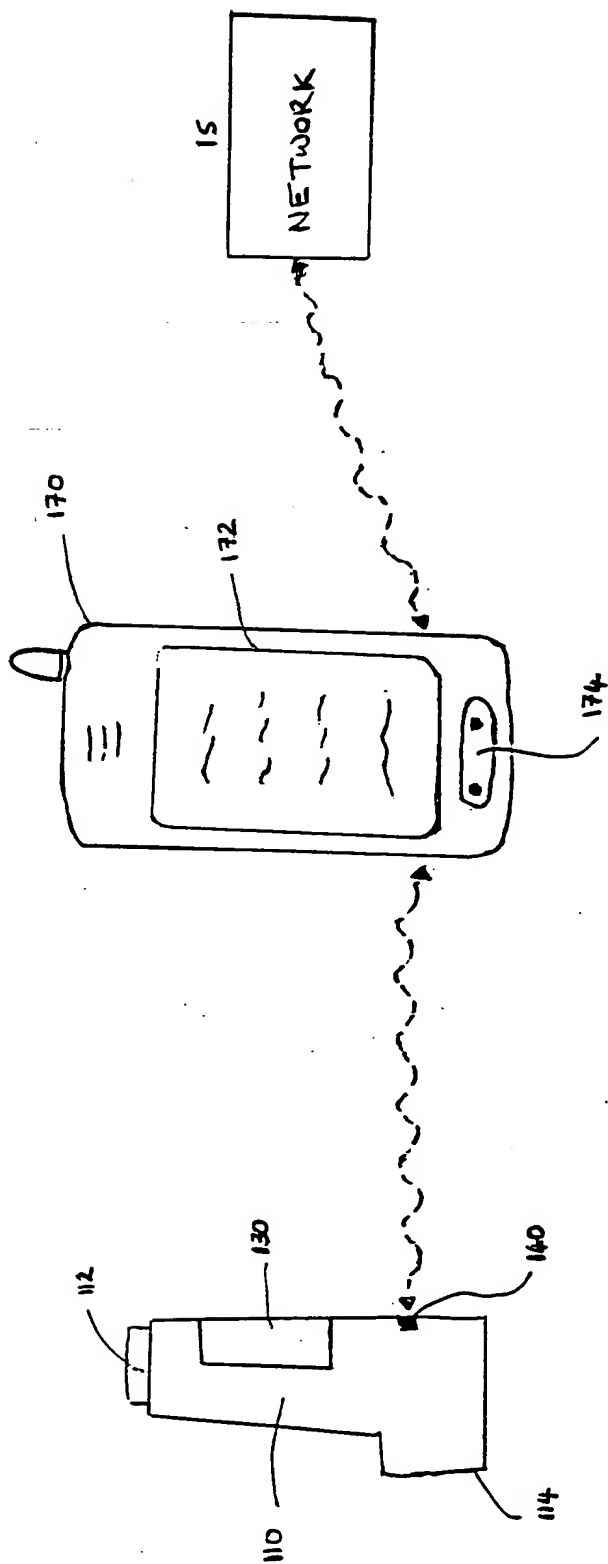
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Fig 2.

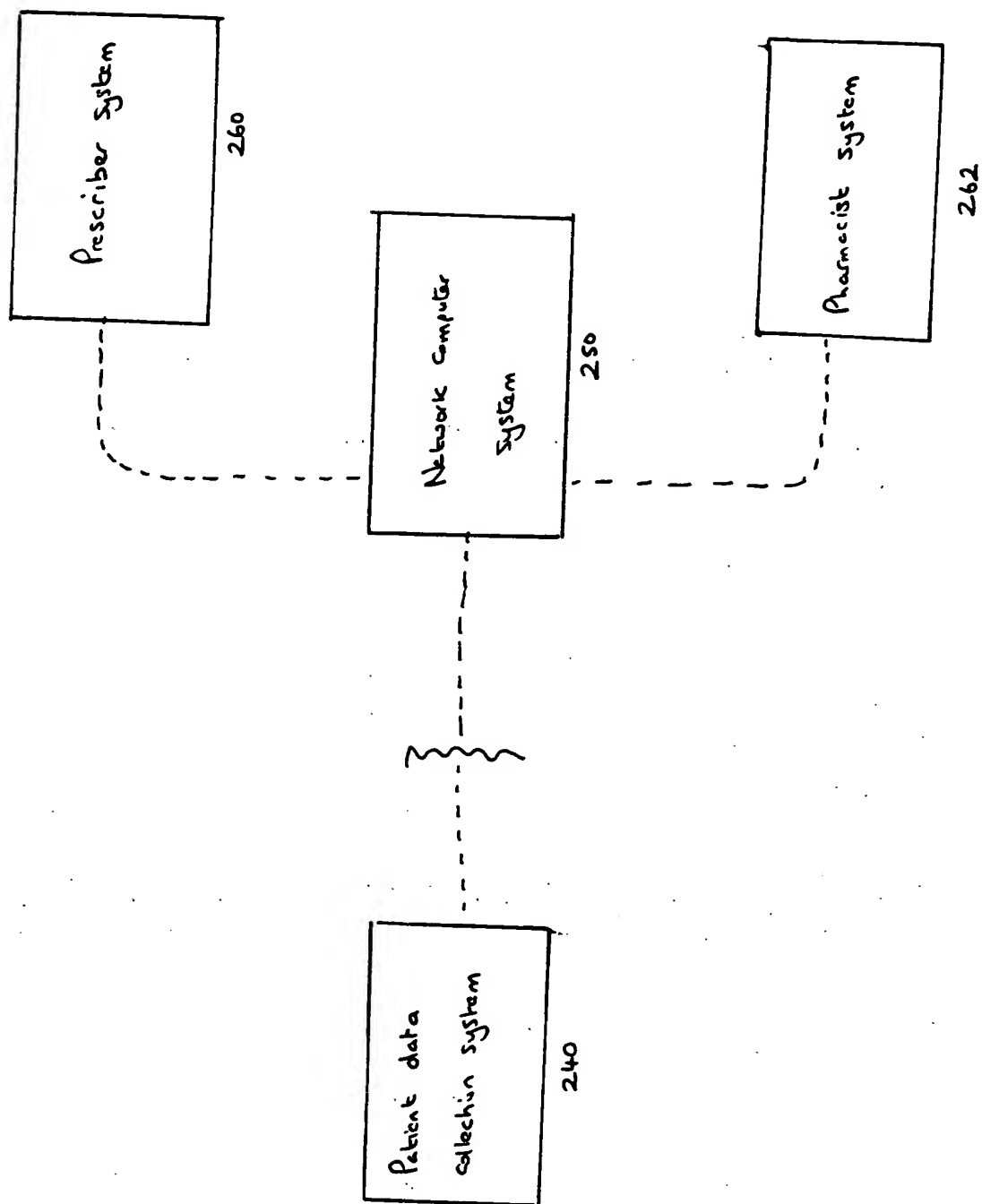
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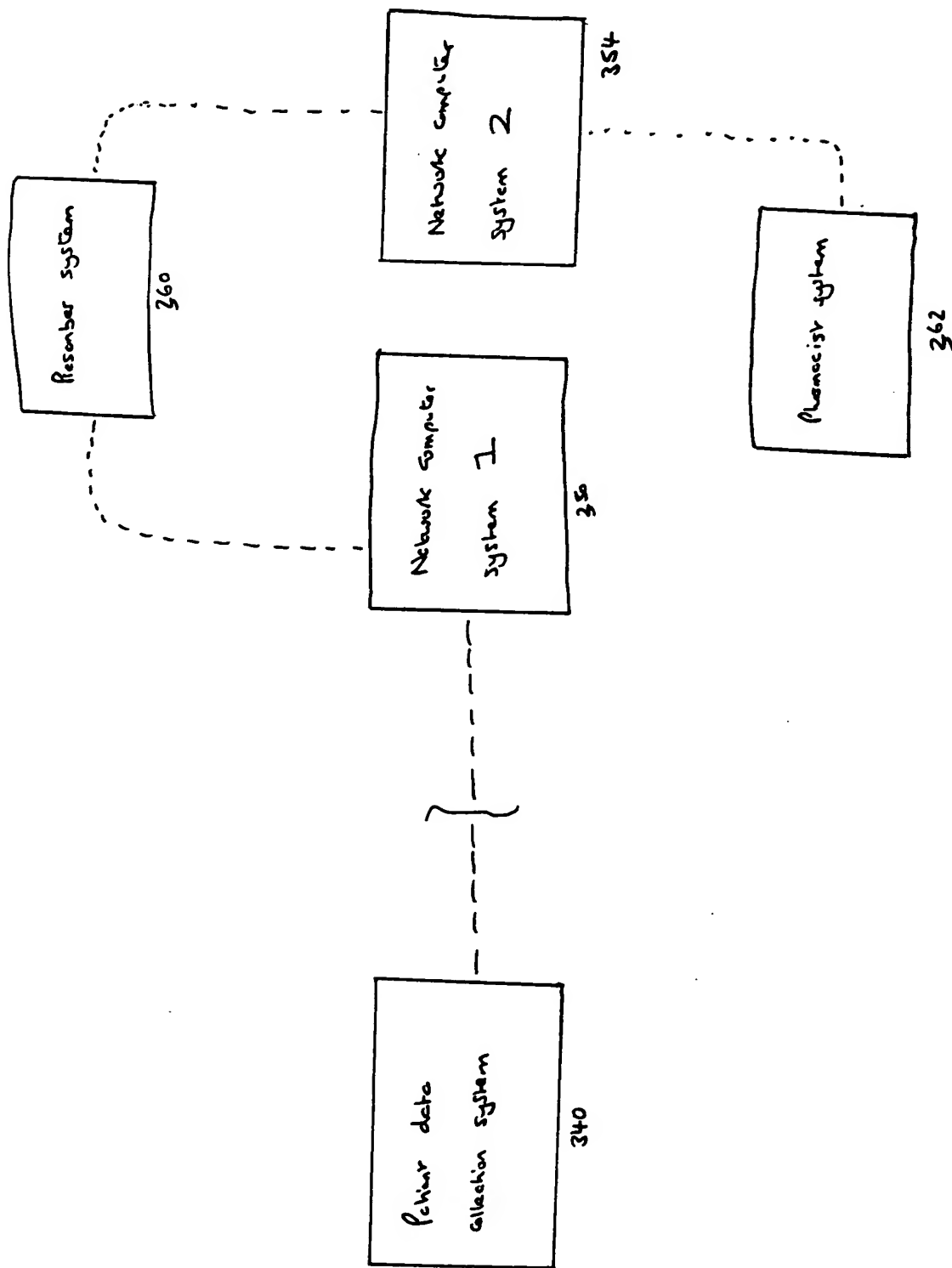
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Fig. 3



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Fig 4.



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